CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

LARGE VOLUME – TACTICAL AND ANALYTICAL COMMITTEE PERIODIC REVIEW PROCESS

1.0 PURPOSE

1.1 Cardinal Health (CAH) Quality and Regulatory Affairs (QRA) Anti-Diversion's Large Volume – Tactical and Analytical Committee (LV-TAC) uses this procedure to identify and assess the top retail purchasers of commonly diverted controlled substances (**e.g.,** Alprazolam 2 mg, Hydrocodone and Oxycodone (A2HO)) or other drugs of interest (ODI) on a periodic basis (**e.g.,** monthly). The purpose of the committee is to conduct a detailed review of these large volume accounts in order to evaluate the likelihood that a customer is engaged in diversion based on "red flags" identified by DEA and other known signs of diversion.

1.2 To comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, and to meet or exceed DEA's expectations of distributors that have been communicated through informal, non-binding communications.

2.0 SCOPE

The scope of this procedure is to perform analytical and tactical assessments of all large retail volume purchasers of controlled substances, as defined below. The business functions impacted are all Pharmaceutical Operations, QRA and Anti-Diversion and Supply Chain Integrity.

3.0 REFERENCES / RELATED DOCUMENTS

MoA	Administrative Memorandum of Agreement (MoA) between Cardinal Health and the DEA effective October 2, 2008
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Help%20%20FAQ/Controlled%20Document%20Resources/DEA_Guidance_Document.pdf"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Help%20%20FAQ/Controlled%20Document%20Resources/DEA_Guidance_Document.pdf"~~ }	Titled "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances" and dated October 20, 2009 downloaded from the DEA Anti-Diversion Website (http://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf) on April 5th, 2012

DEFENDANT EXHIBIT
CAH-WV-00065

4.0 RESPONSIBILITIES

The Large Volume Tactical and Analytical Committee (LV-TAC) will be comprised of:

a. Senior Vice President of Quality & Regulatory Affairs to chair the committee
b. Regulatory Counsel
c. Vice President of Supply Chain Integrity
d. Director of QRA Analytics
e. VP of Sales or designee
f. Outside Counsel (on an as needed basis)

The responsibilities of the LV-TAC include periodic review and scrutiny of large purchasers of commonly diverted Controlled Substances or other drugs of interest (ODI) based on existing information in the QRA documents and current purchase patterns. The committee may direct the QRA Investigations Team or QRA Pharmacists Team to perform further due-diligence using permissible investigative methods (**e.g.,** site-visits, data requests, phone interviews, e-mail interactions). Once all the relevant data/information is obtained, the committee will assess the potential risk for diversion posed by these customers. The committee will then decide to either continue or terminate the ability of customers to purchase controlled substances or ODI from CAH. The Committee may also direct other action(s) concerning large volume customers who the Committee has determined, based on available information, do not appear to be engaged in diversion.

5.0 DEFINITIONS

A2HO — A2HO is an abbreviation for Alprazolam 2 mg, Hydrocodone and Oxycodone products.

Anti-Diversion Customer Profile — A report generated by QRA containing various background, licensing, and analytical metrics relevant to a customer used to assist in the evaluation of threshold events.

Large Purchasers of Controlled Substances — Top retail purchasers of commonly diverted controlled substance pharmaceuticals (e.g. A2HO). This list could be generated for the entire network or by distribution center and will include all CAH pharmacy customers classified as “Retail Pharmacies”. The list could also include other drugs of interest (ODI) depending on geographical, dispensing and/or diversion trends.

Month under review — Generally defined as the previous calendar month OR the month under consideration by the LV-TAC.

Other Drugs of — Other Drugs of Interest may be comprised of other drugs having a high potential for diversion depending upon the geographic region, prescribing and diversion

Interest (ODI)	trends etc.
Site Investigation Reports and Case Notes	Customer site visit investigation and case notes written by QRA Site Visit Investigators containing observations on a customer's prescription filling process, types of controlled substances dispensed, prescriber licensing information and regulatory actions, customer site photographs (if available), and dispensing data summary (if available) reflecting average quantities for commonly diverted controlled substances or ODI dispensed.
Tableau Report	A report generated by the QRA Analytics team with information on a customer's past monthly purchases (**e.g.,** 1 year or more duration) of controlled and non-controlled substances from all of Cardinal Health's Pharmaceutical distribution business units.

6.0 PROCEDURE

6.1 General Information

6.1.1 In accordance with the process below, CAH QRA's LV-TAC meets periodically (**e.g.,** monthly) to assess large purchasers of controlled substances.

6.1.2 The periodic meetings of the LV-TAC review pharmacies for appropriate action(s) based on the procedure described in this SOP and review outstanding issues from prior meetings. In addition, LV-TAC may review site visit results and review prior decisions made by LV-TAC.

6.1.3 On a periodic basis (**e.g.,** monthly) a list of commonly diverted controlled substance (**e.g.,** A2HO) products or ODI purchased by the large volume retail purchasers will be generated for the period under review.

6.2 Review

6.2.1 The committee will be provided with relevant information prior to the meeting to aid in its review. Examples of the information to be provided, when applicable, may include but are not limited to the following information:

a. Purchase Trend Data (**e.g.,** Tableau Report)
b. A copy of the last investigation report and any case notes for the last visit
c. Media reports (**e.g.,** News Articles) and other relevant public media information (**e.g.,** Internet searches on the pharmacy, primary prescribers)

6.2.2 Factors to Consider

6.2.2.1 Numerous factors may be considered to assess the risk of diversion. The factors the LV-TAC may consider for diversion risk assessment are primarily based on the DEA Guidance Document and expertise of the LV-TAC committee members. The factors include but are not limited to the following:

a. Is the pharmacy affiliated with an Internet site that appears to provide prescriptions based on an on-line questionnaire or other questionable practices?
b. Is the pharmacy a legitimate mail order pharmacy (**e.g.,** fills prescriptions for insurance, etc.) or an illegitimate Internet pharmacy (**e.g.,** fills prescription where a valid physician-patient relationship does not exist)?
c. Is the pharmacy licensed in all states into which it mails or dispenses prescription drugs?
d. Do the pharmacists and/or owner(s) appear to understand their corresponding responsibility under 21 CFR §1306.04?
e. Does the pharmacy appear to have adequate controls to prevent diversion, (**e.g.,** using a prescription monitoring program to help the pharmacist assess the legitimacy of patients or prescribers)?
f. Does the pharmacy actively solicit practitioners for more business to be directed to that pharmacy either through internal staff or a private company?
g. What is the ratio of controlled to non-controlled drugs based on dosage units dispensed and/or purchased by the pharmacy on monthly basis?
h. Does the pharmacy order a wide variety of controlled substances? Are those controlled substances purchased evenly dispersed? If not, is there an explanation as to why not?
i. Do the quantities of controlled substances ordered seem reasonable given the size of the pharmacy, the number of prescriptions filled, the hours of operation, and other demographic information,(**e.g.,** does the pharmacy provide services for any specialty customers such as Long Term Health Care, Hospice Centers, Assisted Care Living Facilities, etc. that explain high volume purchases of controlled substances)?
j. Does the pharmacy offer a full assortment of sundries to its customers (**e.g.,** aspirin, snacks, cosmetics, etc.)?
k. Does the pharmacy have security guards on the premises? If so, why?
l. What methods of payment does the pharmacy accept (cash, insurance, Medicaid, Medicare and in what ratios)?
m. Who is the pharmacy's primary supplier of Controlled Substances?
n. Does the pharmacy order Controlled Substances from other suppliers besides CAH? If so, why does it do so? What controlled substances are those?
o. What percentages of controlled substances are purchased from CAH compared to other suppliers?
p. Does the pharmacy fill prescriptions for out-of-state customers? If so, for

how many out-of-state customers does the pharmacy fill (ratio or approximate number)?

q. If the pharmacy fills prescriptions for Pain Management or other specialty practitioners (diet, oncology, etc.), is the pharmacist comfortable with the prescribing practices of the practitioner?
r. Has the pharmacist questioned or been uncomfortable with, the prescribing practices of any practitioner?
s. Has the pharmacy ever refused to fill prescriptions for a practitioner? If so, why and for who?
t. Are there particular practitioners who constitute most of the prescriptions it fills? Who are these practitioners (Name and DEA registration number)?
u. Does the pharmacy have any exclusive contracts, agreements, arrangements, etc., with any particular practitioner, business group, investors, etc.? If so, explain those arrangements and/or obtain copies of those agreements if possible.
v. Is the pharmacist comfortable with the prescribing practices of any or all practitioners for which they fill?
w. Does the pharmacy supply, order for, or sell to any practitioners or other pharmacies?
x. How does the pharmacy sell/transfer controlled substances to other pharmacies or practitioners? Via a prescription, sales invoice, or DEA Form-222? (Transfer by prescriptions is not authorized)

6.3 Decision

6.3.1 The LV-TAC committee will meet periodically (**e.g.,** monthly) to evaluate and make decisions on pharmacies considering, where applicable, the factors listed above. Below are examples of the decisions that could be made by the committee:

a. Allow the pharmacy to continue to purchase controlled substances from CAH and re-evaluate their operations after 12 months
b. Allow the pharmacy to continue to purchase controlled substances from CAH and re-evaluate their operations after 3 months
c. Terminate the pharmacy's ability to purchase controlled substances from CAH and report the pharmacy to DEA
d. Request that the pharmacy provide additional data and/or information. The information may be requested by phone or site visit via a QRA or sales associate
e. Restrict the pharmacy from purchasing certain controlled substance drug families until additional investigation and information is obtained and assurances are provided that no diversion is occurring
f. Adjust the customer's threshold for one or more controlled substances

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 For all customers that have been visited, all site visit investigation reports, site visit case notes, dispensing data report reflecting average quantities for commonly diverted controlled substances or ODI dispensed, prescriber due-diligence and other documentation must be completed and loaded into Content Manager within a reasonable period of time (**e.g.,** 30 calendar days).

7.1.2 Termination notices will be sent to the sales associates, business leaders and applicable regulatory agencies (**e.g.,** DEA, Boards of Pharmacy, state controlled substance agencies).

7.1.3 The Vice President of Supply Chain Integrity will communicate to the members of his team, the decisions made by the team and make assignments, if applicable, to gather any additional data/information needed to complete a review.

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Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Gilberto Quintero; Bob Giacalone				Owner: Michael Moné PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
2961	TBD	New	Yes	Corporate	Other
Other (specify)					
Training assignments to Corporate Anti-Diversion personnel who are involved in the large volume, tactical and analytical committee periodic review process.					
Change Description and Justification					
Initial release of new procedure, PDQRA-CAD-C023 to address the large volume, tactical and analytical committee periodic review process.					